

REMARKS

Claims 33, 34, 36, 39, 40 and 43 were previously pending in this application. By this amendment, Applicant is canceling claims 36, 39, 40 and 43 without prejudice or disclaimer. Claim 33 has been amended to clarify the steps in the method. Support for the amendment can be found on page 17, lines 23-26. New claims 44-46 have been added. Support for new claims 44, 45, and 46 can be found at least at page 17, lines 25-26, page 15, lines 15-28, and page 17, lines 10-11, respectively. As a result claims 33, 34, 44, 45 and 46 are pending for examination with claim 33 being an independent claim. No new matter has been added.

Restriction Election

As discussed in the telephone call between the Examiner and Applicant's representative on March 29, 2004, claims 33 and 34, which are in the group elected by Applicant in the restriction election relate to JNK not to MLK. The Examiner acknowledged in the phone conversation that the inclusion of MLK in the text of the elected claims was an oversight and the Examiner agreed with Applicant's representative that the claims in the elected group relate to methods for assessing a compound's ability to inhibit JNK kinase activity (Claim 33), and methods of claim 33, wherein JNK is JNK1, JNK2, or JNK3, or combinations thereof. Applicant respectfully submits that the correct text of claims 33 and 34 is as provided in the complete pending claim set above.

Information Disclosure Statement

Applicant acknowledges that the Examiner included initialed and signed copies of two Form PTO-1449 forms that were received by the USPTO on April 24, 2002 and March 5, 2003. Applicant notes that references listed as Document numbers AB and AC on the Form PTO-1449 received on April 24, 2002 were not initialed by the Examiner. In the telephone conversation between the Examiner and Applicant's representative on March 29, 2004 the Examiner indicated that the Examiner inadvertently omitted initialing references AB and AC. Applicant respectfully requests that the Examiner please initial these references and provide Applicant with a copy of the initialed and signed forms.

Rejections Under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 33 and 34 under 35 U.S.C. §112 as indefinite. Applicant has amended claim 33 to clarify the claim. Applicant has amended the claim to indicate that “change in physiological status” is change in apoptosis. Applicant asserts that the determination of apoptosis in a sample from the mammal is indicative of the ability of a compound that inhibits JNK kinase activity to inhibit JNK kinase activity in an animal and indicates the compound’s ability to prevent neuronal death. Applicant respectfully requests that the Examiner withdraw the rejection of claims 33 and 34 under 35 U.S.C. §112, second paragraph.

The Examiner also rejected claim 33 under 35 U.S.C. §112 as lacking antecedent basis for the phrase “inhibit MLK kinase activity”. Applicant, as described above with reference to the Restriction Election, submits that correct text of claim 33 includes the phrase “inhibit JNK kinase activity”, not “inhibit MLK kinase activity”. Applicant asserts that the phrase “inhibit JNK kinase activity” does not lack antecedent basis and therefore respectfully requests that the Examiner withdraw the rejection of claim 33 under 35 U.S.C. §112, second paragraph.

Rejections Under 35 U.S.C. §102

The Examiner rejected claims 33 and 34 under 35 U.S.C. §102(b) as anticipated by Lewis et al., (US 5,621,100, the '100 patent).

Applicant respectfully asserts that the '100 patent does not describe the administration of a compound that is a specific inhibitor of a JNK kinase to an animal and therefore the '100 patent does not contain all the elements of the claim and so does not anticipate the claimed invention.

Claim 33, as amended, is drawn to administering a compound that inhibits JNK kinase activity to an animal and the assessment of apoptosis in neuronal tissues of the animal, which can be compared to a control level of apoptosis determined in neuronal tissues from an animal not administered the compound as a measure of the ability of the JNK kinase to inhibit neuronal cell death in the animal. The '100 patent describes testing compound K-252a and derivatives of that compound for their ability to reduce kainate-induced spectrin proteolysis and pyramidal cell death in rodent hippocampus. The '100 patent does not teach the administration of a compound

that specifically inhibits JNK activity for the assessment of the compound's ability to reduce apoptosis of neuronal cells in the animal and therefore, does not anticipate claim 33. Applicant respectfully requests the Examiner withdraw the rejection of claims 33 and 34 under 35 U.S.C. §102(b).

The Examiner rejected claims 33 and 34 under 35 U.S.C. §102(e) as anticipated by Miller et al, (US 6,060,247, the '247 patent).

The '247 patent describes adenovirus vectors that encode a protein that either induces or inhibits apoptosis and describes the use of the vectors to infect cells and then exposing the cells to compounds to identify compounds that inhibit or induce apoptosis, growth, or proliferation. The Examiner indicated that grounds for the rejection are found at col. 7, lines 50-60 of the '247 patent, which indicates that “further testing” may be used to examine identified compounds *in vivo*. The indicated paragraph states that “at late stages testing will be performed *in vivo*...” using methods such as axotomy and ischemia and neurons or neuronal tissue are later isolated for assay. (lines 49-59). Applicant respectfully submits that the '247 patent does not teach *in vivo* testing of compounds that specifically inhibit JNK kinase activity. To anticipate the claimed invention, a reference must teach all the elements included in the claims at issue. Applicant submits that the '247 patent fails to meet this standard for a finding of anticipation.

Applicant respectfully asserts that because the '247 patent does not teach all the elements of claim 33 as amended, the '247 patent does not anticipate the claimed invention. Therefore, Applicant respectfully requests the Examiner reconsider and withdraw the rejection of claims 33 and 34 under 35 U.S.C. §102(e).

The Examiner rejected claims 33 and 34 under 35 U.S.C. §102(a) as anticipated by Qin et al., 1998.

The Qin et al reference describes the administration of quinolinic acid into rat striatum *in vivo* to induce DNA fragmentation and apoptosis. The reference indicates that MK801 (dizocilpine) was administered to test animals to block the DNA fragmentation. The abstract of the Qin et al. reference also identifies that MK801 is an NMDA receptor antagonist. Thus, the

Qin et al reference discloses the administration of an NMDA receptor antagonist to reduce the effect of quinolinic acid *in vivo*.

Instant claim 33 as amended, teaches the administration of a compound that specifically inhibits JNK kinase activity coupled with the assessment of the JNK kinase inhibition on apoptosis in the animal. Applicant respectfully submits that Qin et al reference does not teach that MK801 is a compound that specifically inhibits JNK kinase. Thus, the Qin et al. reference does not teach each element of the instant claims and therefore does not anticipate claims 33 and 34.

Applicant respectfully requests that the Examiner withdraw the rejection of claims 33 and 34 under 35 U.S.C. §102(a) as anticipated by Qin et al.

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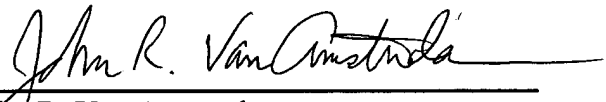
Art Unit: 1651

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's representative at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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